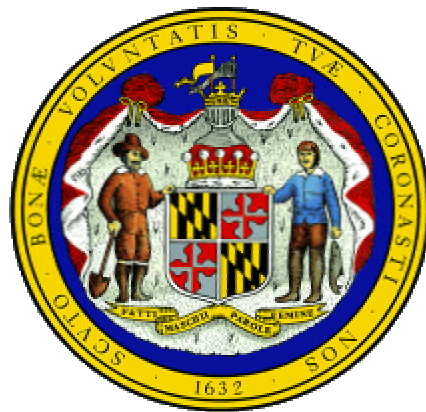


White Paper

Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland



MARYLAND HEALTH CARE COMMISSION

June 2000

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I. INTRODUCTION

A. Background

In Maryland and in the United States as a whole, heart disease is the leading cause of death. During 1998, heart disease accounted for almost one-third of all Maryland resident deaths. While there are many forms of heart disease, coronary heart disease accounts for the majority of all heart disease deaths. The major underlying cause of coronary heart disease is atherosclerosis, which refers to the development of fatty deposits or plaque along the inner walls of the coronary artery. Specialized cardiac care services used in the diagnosis and treatment of coronary heart disease are the focus of the State Health Plan chapter on Cardiac Surgery and Therapeutic Catheterization Services.

Cardiac surgery services addressed in the current State Health Plan principally refer to open heart surgery for adults.¹ Open heart surgery generally refers to cardiac surgery during which a heart-lung machine (i.e., cardiopulmonary bypass) may temporarily assume the functions of the patient's heart and lungs, permitting the cardiac surgeon to repair lesions within the heart or coronary arteries. Diseases of the coronary arteries are treated by an open heart surgical procedure referred to as coronary artery bypass graft (CABG). In this procedure, a piece of the saphenous vein from the leg, or the internal mammary artery from the chest, is extracted and used to bypass the blocked part of the coronary artery and restore the blood supply to the heart. CABG procedures, which are generally performed on patients with blockages in two or more vessels, account for the vast majority of open heart surgery.

This chapter of the State Health Plan also includes percutaneous transluminal coronary angioplasty (PTCA), or therapeutic catheterization services. PTCA, which is performed in the cardiac catheterization laboratory, involves inserting a catheter with balloon into a blocked artery and then inflating the balloon to flatten plaque against the artery wall. After a few seconds, the balloon is deflated and removed. While coronary angioplasty is performed mainly on patients with single vessel coronary artery disease, it is also used to treat patients with multivessel disease. Although angioplasty is most frequently performed on an elective basis, this intervention has gained acceptance as a primary treatment (i.e., primary angioplasty) for certain acute myocardial infarction patients.

B. Purpose of the White Paper

During 2000, the Maryland Health Care Commission will update the State Health Plan for cardiac surgery and therapeutic catheterization services. This *White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland* has been prepared to assist the Commission in the process of updating this component of the State Health Plan by: (1) providing background information on cardiac care services in Maryland; (2) identifying key policy issues in planning and regulating open heart surgery services; (3) examining the impact of alternative policy assumptions; and (4) providing a framework for the Commission to obtain public comment on key policy issues prior to updating the State Health Plan.

¹ The State Health Plan chapter also includes planning policies and CON review standards for pediatric cardiac surgery services.

In identifying and examining the impact of alternative policy assumptions, it is the intent of the paper to encourage public discussion and debate in shaping the policy direction of the updated State Health Plan. While the paper does examine alternative approaches for key planning policies, it is important to recognize that the alternatives identified do not represent the staff recommendation or the full range of policy options that potentially will be considered in the process of updating the plan. It is the expectation of the Commission that the public comment process involved in updating the plan will identify additional policy options and approaches that merit consideration.

D. Invitation for Public Comment

The Commission invites all interested organizations and individuals to participate in the process of updating the State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services. Written comments on this White Paper should be submitted not later than Friday, July 28, 2000 to:

John M. Colmers
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Maryland Health Care Commission
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Baltimore, Maryland 21215
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The Commission also will hold a two-part panel discussion to consider perspectives on planning for specialized cardiac care services from representatives of hospitals that currently provide open heart surgery and representatives of hospitals that would like to develop new open heart surgery programs. This panel discussion will be held at the regular July public Commission meeting:

1:00 p.m. – 3:00 p.m.
Friday, July 21, 2000
4201 Patterson Avenue
Conference Room 108-109
Baltimore, Maryland 21215

The written comments received on the White Paper and the presentations made in the panel discussion will be used by the Commission staff to prepare a draft updated State Health Plan chapter on cardiac surgery and therapeutic catheterization services. This draft plan will be presented at the September 15, 2000 Commission meeting. The Commission will circulate this draft for public comment prior to formally promulgating the plan through the regulatory process.

D. Planning for Open Heart Surgery Services in Maryland

Under Maryland health planning law, the establishment of new open heart surgery programs requires Certificate of Need (CON) approval. To guide public policy governing the establishment of new open heart surgery services, the State Health Plan contains planning policies, a need projection, and criteria and standards for reviewing CON applications. The current State Health Plan chapter, COMAR 10.24.17, governing cardiac surgery services was developed during 1996-1997 and became effective December 1, 1997. The need projections included in that plan forecast open heart surgery cases for the target year 1999.

The process used to develop State health policy governing cardiac surgery and therapeutic catheterization services has included consultation with experts in cardiology and cardiovascular surgery from throughout Maryland. In 1996-1997, the former Health Resources Planning Commission convened a 15-member Technical Advisory Committee as part of an initiative designed to prepare State Health Plan chapters for several highly specialized health services. The findings and recommendations of this Technical Advisory Committee were used in preparing the current State Health Plan. The Technical Advisory Committee established in 1996-1997 recommended that an assessment of the impact of changes in cardiovascular care be conducted by the Commission every two years with the assistance of an advisory group. Consistent with this recommendation, the Commission reconvened the Technical Advisory Committee in December 1998. This Technical Advisory Committee, which completed its work in December 1999, was composed of 24 members with expertise in cardiac care services from throughout Maryland as well as the adjacent District of Columbia. The recommendations of the reconvened Technical Advisory Committee are being considered in the process now underway to update the State Health Plan chapter.

E. Organization of the White Paper

The White Paper is organized in four major sections. Following this Introduction, Part II of the paper contains an overview of specialized cardiac care services, including a description of the Maryland cardiac care system and an analysis of trends in the utilization of cardiac surgery and coronary angioplasty services. In Part III of the White Paper, a series of planning and regulatory issues are identified together with analysis of the impact of alternative policy options. Those planning and regulatory issues include: (1) need projection policies; (2) quality of care; (3) cost of care; (4) access to care; and (5) other policies. A summary of the policy options is provided in Part IV. The appendices to the White Paper include: (1) detailed data on the volume of open heart surgery procedures by location of hospitalization and jurisdiction of patient residence; and (2) the calculation of projected open heart surgery cases for target year 2002 using the current need projection methodology with alternate use rate assumptions.

II. SPECIALIZED CARDIAC CARE SERVICES: OVERVIEW

A. Maryland Cardiac Care System

Specialized cardiovascular services to diagnose and treat heart disease are a major component of the acute care hospital system in Maryland. Diagnostic cardiac catheterization laboratories are currently operated by 33 of the 47 non-federal, acute care hospitals in Maryland. In addition, two federal hospitals, Walter Reed Army Medical Center and Bethesda Naval Hospital, provide specialized cardiac care services to eligible patients.² As indicated in Table 1, diagnostic cardiac catheterization services are available at four of the five acute care hospitals in the Western Maryland region. In the Metropolitan Washington area, eight of the 13 Maryland acute care hospitals operate catheterization laboratories. Eighteen of the 22 licensed acute care hospitals in the Metropolitan Baltimore region provide cardiac catheterization services. On the Eastern Shore, three of the seven hospitals maintain catheterization laboratories.

Eight Maryland hospitals currently provide open heart surgery and therapeutic catheterization services. Five of those hospitals are located in the Metropolitan Baltimore region of the State: Johns Hopkins University Hospital (Baltimore City); St. Joseph Medical Center (Baltimore County); Sinai Hospital of Baltimore (Baltimore City); Union Memorial Hospital (Baltimore City); and the University of Maryland Hospital (Baltimore City). In the Metropolitan Washington area, two Maryland hospitals provide open heart surgery and therapeutic catheterization services: Prince George's Hospital Center, located in Prince George's County; and Washington Adventist Hospital, located in Montgomery County. Peninsula Regional Medical Center, located in Wicomico County on the Eastern Shore, also provides adult open heart surgery services and angioplasty services. Cardiac surgery services for pediatric patients are provided at Johns Hopkins University Hospital and University of Maryland Hospital.

Table 1
Distribution of Non-Federal Acute Care Hospitals Providing Specialized Cardiovascular Care by Type of Service and Region: Maryland, 2000

Region	Licensed Acute Care Hospitals	Diagnostic Catheterization/ OHS/ Angioplasty	Diagnostic Catheterization/ C-Port Study	Diagnostic Catheterization Only	Hospitals Providing Specialized Cardiac Care
Western Maryland	5	0	0	4	4
Metro Washington	13	2	1	5	8
Metro Baltimore	22	5	2	11	18
Eastern Shore	7	1	1	1	3
Maryland Total	47	8	4	19	33

² Federal hospitals are not regulated under the Maryland Certificate of Need program.

Three of the eight Maryland adult open heart surgery and angioplasty programs have been established since 1989. Sinai Hospital of Baltimore and Prince George's Hospital Center were awarded Certificates of Need to establish open heart surgery programs in 1989. Both hospitals began offering open heart surgery and angioplasty services in 1990. A Certificate of Need for an open heart surgery program was approved for Union Memorial Hospital in 1993. The open heart surgery and angioplasty program at Union Memorial Hospital became operational in 1994. In September 1999, a Certificate of Need to develop an open heart surgery program was awarded to the Western Maryland Health System to establish a program at Sacred Heart Hospital in Allegany County. This program is expected to become operational in the Fall of 2000.

At present, four Maryland hospitals with cardiac catheterization laboratories provide primary angioplasty services as participants in the registry of the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) study. One of these hospitals is located in Montgomery County (Suburban Hospital), one is located in Talbot County (Memorial Hospital of Easton), and two are located in the Baltimore region (Johns Hopkins Bayview Medical Center and St. Agnes Hospital). Several additional Maryland hospitals are expected to initiate participation in the registry of C-PORT (referred to as C-PORT II) during the next several weeks.

Maryland residents are also served by specialized cardiovascular services located in Washington, D.C. and other adjacent States. In Washington, D.C., four hospitals (George Washington University Hospital, Georgetown University Hospital, Howard University Hospital, and Washington Hospital Center) provide open heart surgery and angioplasty services for adults. Two hospitals in Washington, D.C., Children's Hospital National Medical Center and Georgetown University Hospital, provide cardiac surgery services for pediatric patients. Specialized cardiac care services in Delaware, West Virginia, and Virginia also serve Maryland residents.

In addition to cardiac surgery and angioplasty programs, chest pain centers have been established to improve community hospitals' capabilities in effectively treating possible heart attack patients. According to a survey conducted by the American College of Emergency Physicians, nine percent of hospital emergency rooms have chest pain units.³ Various names have been given to these programs, including chest pain emergency room, chest pain center, chest pain evaluation unit, and emergency department monitored observation bed. These programs have developed approaches to improving the care of the patient with chest pain. In Maryland, between 12 and 15 hospitals have established the protocols, designated space, equipment and personnel, and embarked on community education efforts associated with successful chest pain centers, although the exact number is not known.⁴

³ Graff, L. Joseph, T. et al., American College of Emergency Physicians Information Paper: Chest Pain Units in Emergency Departments-A Report from the Short-Term Observation Services Section. *The American Journal of Cardiology*. Vol. 76, November 15, 1995, 1036-1039.

⁴ Conversation with Raymond Bahr, M.D., Medical Director, Paul Dudley White Coronary Care System, St. Agnes Hospital, Baltimore, Maryland.

B. Utilization Trends: Open Heart Surgery and Coronary Angioplasty

In 1999, hospitals in Maryland and Washington, D.C. performed 9,076 adult open heart surgery cases. (Table 2 displays trends in the number of adult open heart surgery cases over the six-year period, 1994-1999.) Although there were substantial annual increases in the total volume of open heart surgery cases performed between 1994-1995, more recent data indicate a pattern of stable utilization. In each of the past two years, the volume of open heart surgery cases performed in Maryland and Washington, D.C. has increased by 1.5 percent or less. By comparison, between 1994-1995 and 1995-1996, open heart surgery volumes increased by 6.7 and 12.0 percent, respectively. Analysis of utilization trends by region shows that the number of adult open heart surgery cases performed in the Metropolitan Baltimore region peaked in 1997 and has declined in both 1998 and 1999. In the Metropolitan Washington region, the growth in annual cardiac surgical volumes continued through 1998 before moderating in 1999. Moderate annual increases in utilization have occurred throughout the six-year period, 1994-1999, for the Eastern Shore region.

About 55 percent of the open heart surgery cases performed in Maryland and Washington, D.C. hospitals during 1999 were for patients 65 years of age and older. Patients in the 45-64 year age group accounted for about 40 percent of total open heart surgery cases in 1999. The remaining 5 percent of cases were for patients in the 15-44 year age group. On average, patients undergoing open heart surgery had a hospital length of stay of 9.51 days during 1999.

Analysis of data on trends in the utilization of percutaneous transluminal coronary angioplasty shows that 13,365 procedures were performed during calendar year 1999 in Maryland and Washington, D.C. hospitals. (Table 3 provides data on the volume of coronary angioplasty procedures performed between 1994-1999.) Similar to the experience with open heart surgery services, more recent data show a pattern of moderate annual increases in overall volumes. While angioplasty volumes increased by almost 11 percent between 1996-1997 (from 10,920 to 12,094), data for the most recent time period indicate that volumes increased by only 4 percent between 1998-1999.

For coronary angioplasty services, 48.5 percent of total procedures in Maryland and Washington, D.C. hospitals were for patients 65 years of age and older during calendar year 1999. The 45-64 year age group accounted for 45.7 percent of coronary angioplasty cases while the 15-44 year age group comprised the remaining 5.8 percent. Patients undergoing coronary angioplasty required hospitalization for an average of 3.05 days in 1999.

Table 2
Adult Open Heart Surgery Cases by Hospital:
Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	1995	1996	1997	1998	1999
Metropolitan Washington Region						
Prince George's Hospital Center	59	81	90	61	91	120
Washington Adventist Hospital	925	723	839	899	817	817
<i>Total Maryland</i>	<i>984</i>	<i>804</i>	<i>929</i>	<i>960</i>	<i>908</i>	<i>937</i>
Georgetown University Hospital	542	444	451	328	301	140
George Washington University Hospital	148	150	118	65	85	----
Howard University Hospital	----	----	----	43	46	50
Washington Hospital Center	1,669	1,808	2,041	2,405	2,709	2,950
<i>Total Washington, D.C.</i>	<i>2,359</i>	<i>2,402</i>	<i>2,610</i>	<i>2,841</i>	<i>3,141</i>	<i>3,140</i>
Metropolitan Washington Total	3,343	3,206	3,539	3,801	4,049	4,077
Metropolitan Baltimore Region						
St. Josephs Hospital	842	1,008	1,269	1,388	1,411	1,308
Johns Hopkins Hospital	1,116	1,050	1,047	1,134	1,146	1,100
Sinai Hospital of Baltimore	473	444	577	416	477	541
Union Memorial Hospital	198	723	777	838	778	893
University of Maryland Hospital	785	713	818	775	553	596
Metropolitan Baltimore Total	3,414	3,938	4,488	4,551	4,365	4,438
Eastern Shore Region						
Peninsula Regional Medical Center	360	448	475	482	536	561
TOTAL	7,117	7,592	8,502	8,834	8,950	9,076

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1999.)

Table 3
Percutaneous Transluminal Coronary Angioplasty Cases by Hospital:
Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	1995	1996	1997	1998	1999
Metropolitan Washington Region						
Prince George's Hospital Center	155	222	232	252	302	318
Washington Adventist Hospital	1,833	1,952	1,806	1,933	1,996	1,836
<i>Total Maryland</i>	<i>1,988</i>	<i>2,174</i>	<i>2,038</i>	<i>2,185</i>	<i>2,298</i>	<i>2,154</i>
Georgetown University Hospital	346	401	354	173	141	80
George Washington University Hospital	----	----	----	295	259	----
Howard University Hospital	----	----	----	32	52	56
Washington Hospital Center	3,041	3,066	3,048	3,332	3,683	3,986
<i>Total Washington, D.C.</i>	<i>3,387</i>	<i>3,467</i>	<i>3,402</i>	<i>3,832</i>	<i>4,135</i>	<i>4,122</i>
Metropolitan Washington Total	5,375	5,641	5,440	6,017	6,433	6,276
Metropolitan Baltimore Region						
St. Joseph's Hospital	1,269	1,528	1,664	1,592	1,820	1,775
Johns Hopkins Hospital	1,160	811	822	1,052	1,039	1,151
Sinai Hospital of Baltimore	652	740	757	778	764	848
Union Memorial Hospital	142	450	560	818	1,060	1,391
University of Maryland Hospital	571	541	579	591	588	538
Metropolitan Baltimore Total	3,794	4,070	4,382	4,831	5,271	5,703
Eastern Shore Region						
Peninsula Regional Medical Center	776	909	1,098	1,246	1,153	1,386
TOTAL	9,945	10,620	10,920	12,094	12,857	13,365

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1994-1996 and 1999.)

III. POLICY AND REGULATORY ISSUES IN PLANNING OPEN HEART SURGERY SERVICES: AN EXAMINATION OF ALTERNATIVE OPTIONS

A. Need Projection Policies

A major goal of the State Health Plan is to ensure appropriate changes in the capacity of services regulated by the CON program. One of the principal tools used to support this goal is the service-specific need projection methodology. The service-specific need projection methodology is used to determine whether the expected future utilization of a particular service will be sufficient to support new capacity. For open heart surgery services, the need projection methodology contains several key components: (1) definition of planning regions; (2) length of the planning horizon; (3) use rate assumptions in projecting future cases; (4) measurement of existing program capacity; and (5) patient migration assumptions.

1. Definition of Planning Regions

While many services addressed in the State Health Plan are suitable for projecting need at the jurisdictional level, for highly specialized services, such as open heart surgery, a larger population base is necessary to ensure that programs have adequate caseloads. As a consequence, open heart surgery services are planned on a regional basis. Given this consideration, the appropriate geographic regions for analyzing future utilization are an important component of the State Health Plan need projection methodology. Alternative policy options for defining open heart surgery planning regions are outlined in Table 4 and discussed below.

◆ Option 1: Current Planning Regions

The current State Health Plan establishes four regional service areas for planning adult open heart surgery services: Western Maryland; Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore. While there are currently no open heart surgery programs located in Western Maryland, a program has been approved and is expected to become operational later this year. In the Metropolitan Washington Region (excluding Northern Virginia), six hospitals offer cardiac surgery services, including two hospitals in Maryland and four hospitals in Washington, D.C. Five hospitals in the Metropolitan Baltimore Region provide cardiac surgery services, including four hospitals in Baltimore City and one hospital in Baltimore County. On the Eastern Shore, one hospital offers cardiac surgery services. With the exception of Peninsula Regional Medical Center, located on the Eastern Shore, and the program to be established in Western Maryland, cardiac surgery programs currently operating are located in the two major metropolitan areas of the state.

The four regions used in the current State Health Plan reflect naturally occurring geographic markets for healthcare as well as historical physician referral and patient migration patterns. Because highly specialized services are concentrated in a smaller number of hospitals, patients routinely cross jurisdictional as well as state boundaries to receive this care. Analysis of patient migration patterns indicate, for example, that about 75 percent of the patients using Baltimore City open heart surgery programs lived outside of the city during 1999. Data for Washington, D.C. open heart surgery programs show similar patient migration patterns.

Table 4
Comparison of Alternate Options for Defining Open Heart Surgery Planning Regions

Option	Western Maryland	Metropolitan Baltimore	Metropolitan Washington	Eastern Shore
Option 1: Current State Health Plan	Allegany County Frederick County Garrett County Washington County	Anne Arundel Co. Baltimore County Baltimore City Carroll County Harford County Howard County	Montgomery County Calvert County Charles County Prince George's Co. St. Mary's County Washington, D.C.	Caroline County Cecil County Dorchester County Kent County Queen Anne's Co. Somerset County Talbot County Wicomico County Worcester County
<i>Total Population (1998)(2) Open Heart Surgery Programs</i>	396,481 1	2,389,275 5	2,388,554 6	365,737 1
Option 2: Redefine Metropolitan Washington and Baltimore Regions Consistent with Federal Designations	Allegany County Garrett County Washington County	Anne Arundel Co. Baltimore County Baltimore City Carroll County Harford County Howard County Queen Anne's Co.	Montgomery County Calvert County Charles County Prince George's Co. St. Mary's County Frederick County Washington, D.C. Virginia (1) Alexandria City Arlington County Clarke County Culpeper County Fairfax County Fauquier County King George Co. Loudoun County Prince William Co. Spotsylvania Co. Stafford County Warren County West Virginia Berkeley County Jefferson County	Caroline County Cecil County (3) Dorchester County Kent County Somerset County Talbot County Wicomico County Worcester County
<i>Total Population (1998)(2) Open Heart Surgery Programs</i>	214,212 1	2,483,952 5	4,673,902 10	326,330 1
Option 3: Redefine Metropolitan Washington and Baltimore Regions Consistent with Federal Designations (Exclude Out-of-State Areas)	Allegany County Garrett County Washington County	Anne Arundel Co. Baltimore County Baltimore City Carroll County Harford County Howard County Queen Anne's Co.	Montgomery County Calvert County Charles County Prince George's Co. St. Mary's County Frederick County	Caroline County Cecil County (3) Dorchester County Kent County Somerset County Talbot County Wicomico County Worcester County
<i>Total Population (1998)(2) Open Heart Surgery Programs</i>	214,212 1	2,483,952 5	2,047,699 2	326,330 1

(1) The Virginia jurisdictions included the metropolitan statistical area include the following independent cities: Fairfax; Falls Church; Fredericksburg; Manassas; and Manassas Park.

(2) Population estimates are from the Population Estimates Program, Population Division, U.S. Census Bureau, July 1, 1998; and the Maryland Office of Planning, updated 2/00.

(3) Although Cecil County is designated as part of the Wilmington-Newark metropolitan statistical area, it is included in the Eastern Shore region under Options 2 and 3.

◆Option 2: Redefine the Metropolitan Washington and Baltimore Regions Consistent with Federal Designations

An alternative approach to open heart surgery planning regions would be to maintain the four regions but redefine the Metropolitan Washington and Baltimore regions consistent with generally accepted Federal guidelines for metropolitan statistical areas from the Federal Office of Management and Budget (OMB). Metropolitan areas are defined by OMB as a standard for collection and presentation of statistics. The general concept of a metropolitan area is that of a core area containing a large population nucleus, together with adjacent communities having a high degree of economic and social integration with the core area. For the Metropolitan Washington region, this change would result in adding jurisdictions in Virginia/West Virginia that are considered part of the metropolitan statistical area. In addition, Frederick County in Maryland, which is part of the Western Maryland region in the current plan, would be added to the Metropolitan Washington region. For the Metropolitan Baltimore region, use of this definition would add Queen Anne's County, which is currently included with the Eastern Shore region. This change would add four open heart surgery programs (Fairfax Hospital, Arlington Hospital, Alexandria Hospital, and Mary Washington Hospital) located in the Virginia portion of the Metropolitan Washington area to the inventory. While the inclusion of Northern Virginia and West Virginia jurisdictions would be beneficial from the standpoint of reflecting the "true" Metropolitan Washington region market, it could be argued that the comparatively small number of Maryland residents served by Northern Virginia open heart surgery programs makes this change potentially of marginal benefit.

◆Option 3: Redefine the Metropolitan Washington and Baltimore Regions Consistent with Federal Designations (Exclude Out-of-State Areas)

Another approach to the definition of planning regions would be to maintain the four regions with the redefinition of the Metropolitan Washington and Baltimore regions, but exclude the out-of-state components. For the Metropolitan Washington region, this change would exclude Washington, D.C. and the jurisdictions in Virginia and West Virginia. The inventory of open heart surgery programs would be modified significantly under this option given the number of programs located in Washington, D.C. (four programs) and Virginia (four programs). Modification of the planning regions to exclude out-of-state areas could be based on the view that open heart surgery and PTCA services have evolved to the point where they are no longer highly specialized, tertiary services requiring regionalization. The exclusion of out-of-state areas from cardiac surgery planning regions could also be based on the view that hospitals not subject to rate regulation by the HSCRC or licensing by the Office of Health Care Quality should not be included in the State Health Plan inventory of cardiac surgery programs. While it could be argued that it is not unreasonable to exclude out-of-state providers from the State Health Plan, historical patient migration patterns indicate that a substantial number of Maryland residents are served by programs in Washington, D.C. In 1999, for example, about 66 percent of the patients undergoing open heart surgery in Washington, D.C. programs were Maryland residents. Given this circumstance, it could be argued that it would be difficult to develop a comprehensive plan for cardiac care services if a large proportion of the service providers for the population are excluded.

2. Length of the Planning Horizon

A second component of the need projection policy involves the length of the planning horizon used to forecast the volume of expected open heart surgery cases. The duration of this time period is important because it is a key factor in establishing the framework for re-examination of the plan. While traditionally a five-year planning horizon has been used for the State Health Plan, for specialized cardiac care services a shorter, three-year planning horizon is used in the current plan. There are a number of policy options for establishing the planning horizon that will be used in the update of the open heart surgery plan chapter. Two of those options are discussed below:

◆Option 1: Three-Year Planning Horizon

In the current open heart surgery plan, the base year of the need projection is 1996; the target year is 1999. This shorter, three-year planning horizon for the need projection was established based on the recommendations of the technical advisory committee. In their 1997 report, the technical advisory committee recommended that an assessment of emerging techniques for the medical and surgical treatment of heart disease be conducted every two years to ensure that the State Health Plan remains responsive to potential changes in medical practice. The use of this shorter planning horizon also reflects the fact that the establishment of this service generally does not require major facility construction. As a consequence, it is feasible to staff and begin operating a new program within a relatively short period of time. If a three-year planning horizon is used in updating the plan, the base year of the new need projection would be 1999 and the target year would be 2002. A short planning horizon has the potential advantage of allowing the Commission to monitor trends in the utilization of cardiac services and revisit decisions if there are significant changes in those trends. On the other hand, depending on the length of time required for adoption of the plan, a three-year planning horizon may be more abbreviated than would be preferable.

◆Option 2: Five-Year Planning Horizon

Under the health planning statute, the Commission is required to update the State Health Plan at least every five years. Given this statutory language, it clearly would not be inappropriate to use a five-year planning horizon for the open heart surgery need projection. If a five-year planning horizon is used in updating the plan, the base year of the new need projection would be 1999 and the target year would be 2004. The use of a longer period between the base and target year of the need projection has the potential advantage of providing greater stability with respect to implementing recommendations included in the plan. On the other hand, this longer planning horizon could potentially make it more difficult to adequately consider emerging trends in the management and treatment of coronary heart disease.

3. Use Rate Assumptions in Projecting Future Cases

Assumptions about future use rates, or the expected volume of cases per 100,000 population, are a key component of the need projection methodology. Table 5 shows trends in adult open heart surgery use rates for Maryland residents by age group (15-44 years, 45-64 years, and 65 years and over) over the six-year period 1994-1999 based on the current planning regions for cardiac surgery. There are substantial differences in open heart surgery use rates across planning regions. Among the 65 and over age group, for example, use rates per 100,000 population in 1999 ranged from 608.38 in the Eastern Shore region to 794.66 in the Metropolitan Baltimore region. The differences between the low and high use rates observed across regions is due in part to differences in physician practice patterns with respect to treating coronary heart disease.

A comparison of the impact of alternate use rate assumptions on future open heart surgery projections based on current planning regions is provided in Table 6. (Appendix II provides a series of detailed tables showing the steps involved in applying the use rate assumptions under the current methodology for each option discussed below.)

◆ Option 1: 1997-1999 Trended, Regional Use Rates (Current Methodology)

Policy 4.0 of the State Health Plan indicates that the Commission will use regional age-specific use rates in projecting future open heart surgery cases to accurately reflect regional differences in population characteristics, physician practice patterns, and other factors influencing utilization. This policy recognizes that substantial differences in use rates for open heart surgery among the four regional service areas would be obscured with the use of statewide rates. The current methodology (Refer to Figure 1) calculates the average annual change in regional, age-specific use rates per 100,000 population over the most recent three years and then compounds that rate of change between the base and target year to estimate a projected use rate. This projected use rate is then applied to the projected target year population by age group in three of the four regional service areas: Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore. For the Western Maryland region, which does not currently have an open heart surgery program, the State Health Plan uses base year (1999) age-specific use rates in projecting future cases.

In the current plan, the use rate experience over the three-year period, 1994-1996, was used to project 1999 rates. A comparison of the projected 1999 use rates and open heart surgery cases with actual 1999 experience is provided in Table 7. This analysis shows that, with the exception of 15-44 and 65 year and over age groups on the Eastern Shore and the 65 year and over age group in the Metropolitan Washington area, all of the projected 1999 use rates were well above the actual utilization experience. As a result, projected total 1999 open heart surgery cases were about 12 percent higher than the actual utilization experience. The greatest difference between projected and actual cases occurred for the Baltimore region. For the Metropolitan Baltimore region, projected 1999 cases were about 21 percent higher than the number of cases actually performed during the reporting period.

Updating projected open heart surgery cases using the methodology in the current State Health Plan with more recent data (1997-1999) indicates that the overall volume will increase slightly from 9,076 to 9,298 open heart surgery cases between 1999 and 2002.

Table 5
Adult Open Heart Surgery Use Rates Per 100,000 Population by Age Group and Region:
Maryland, 1994-1999

Region/Age Group	15-44 Years		45-64 Years		65+ Years	
	Use Rate	% Change	Use Rate	% Change	Use Rate	% Change
WESTERN MARYLAND						
1994	10.56	-----	228.29	-----	603.24	-----
1995	24.64	133.33%	343.87	50.63%	668.64	10.84%
1996	20.50	-16.80%	336.44	-2.16%	713.93	6.77%
1997	21.25	3.66%	314.54	-6.51%	777.99	8.97%
1998	14.80	-30.35%	260.63	-17.14%	734.91	-5.54%
1999	8.31	-43.85%	298.07	14.37%	632.32	-13.96%
<i>Average Use Rate, 1994-1996</i>	18.57		302.87		661.94	
<i>Average Use Rate, 1997-1999</i>	14.79		291.08		715.07	
METRO WASHINGTON						
1994	9.64	-----	177.86	-----	529.37	-----
1995	9.86	2.28%	163.26	-8.21%	510.28	-3.61%
1996	11.24	14.00%	187.45	14.82%	557.56	9.27%
1997	9.93	-11.65%	193.07	3.00%	626.90	12.44%
1998	14.03	41.29%	191.77	-0.67%	653.71	4.28%
1999	12.05	-14.11%	195.73	2.06%	647.56	-0.94%
<i>Average Use Rate, 1994-1996</i>	10.25		176.19		532.40	
<i>Average Use Rate, 1997-1999</i>	12.00		193.52		642.72	
METRO BALTIMORE						
1994	13.22	-----	257.09	-----	622.22	-----
1995	16.28	23.15%	269.14	4.69%	658.62	5.85%
1996	17.09	4.98%	280.99	4.40%	766.79	16.42%
1997	18.42	7.78%	292.70	4.17%	821.86	7.18%
1998	18.10	-1.74%	254.62	-13.01%	812.58	-1.13%
1999	16.33	-9.78%	259.45	1.90%	794.66	-2.21%
<i>Average Use Rate, 1994-1996</i>	15.53		269.07		682.54	
<i>Average Use Rate, 1997-1999</i>	17.62		268.92		809.70	
EASTERN SHORE						
1994	12.06	-----	238.56	-----	410.26	-----
1995	18.91	56.80%	222.17	-6.87%	407.17	-0.75%
1996	10.69	-43.47%	246.52	10.96%	515.44	26.59%
1997	12.03	12.54%	216.01	-12.38%	587.05	13.89%
1998	14.01	16.46%	212.98	-1.40%	651.97	11.06%
1999	19.32	37.90%	232.47	9.15%	608.38	-6.69%
<i>Average Use Rate, 1994-1996</i>	13.89		235.75		444.29	
<i>Average Use Rate, 1997-1999</i>	15.12		220.49		615.80	
MARYLAND						
1994	11.94	-----	227.01	-----	602.26	-----
1995	15.13	26.72%	235.11	3.57%	621.43	3.18%
1996	14.72	-2.71%	248.52	5.70%	675.50	8.70%
1997	14.95	1.56%	251.77	1.31%	736.71	9.06%
1998	16.01	7.09%	228.56	-9.22%	741.73	0.68%
1999	14.27	-10.87%	236.63	3.53%	716.73	-3.37%
<i>Average Use Rate, 1994-1996</i>	13.93		236.88		633.06	
<i>Average Use Rate, 1997-1999</i>	15.08		238.99		731.72	

Source: Maryland Health Care Commission (Use rates reflect: (1) open heart surgery cases performed on Maryland residents in Maryland and Washington, D.C. hospitals; (2) population estimates from the Maryland Office of Planning, preliminary revised 6/95 for 1994-1996 rates and updated 2/00 for 1997-1999 rates)

FIGURE 1

OVERVIEW: NEED PROJECTION METHODOLOGY FOR ADULT CARDIAC SURGERY SERVICES

Step 1: Trending of Maryland Open Heart Surgery Use Rates to the Target Year

- Calculate the rate of open heart surgery for Maryland residents, except for Western Maryland, for each of the three most recent years of available data for each age group by dividing the total number of open heart surgery cases performed in each age group by the corresponding Maryland population.
- Calculate the average annual percentage change in open heart surgery use rates in each age group by summing the percentage change in use rates between each of the years for each age group, and dividing by the number of years minus one.
- Calculate the target year open heart surgery use rate for each age group by compounding the average annual percentage change in open heart surgery use rate for each age group from base to target year in the following way: multiply the average annual percentage change in open heart surgery use rate for each age group by the use rate in the base year, and by the resulting use rate in each year thereafter up to the third year.

Step 2: Projection of Total Need for Adult Open Heart Surgery for Maryland Residents

- Calculate the projected number of open heart surgery cases in the target year for Maryland residents of each Regional Service Area, except Western Maryland, by multiplying the projected target year open heart surgery use rate for each age group by the target year population in the corresponding age group in each region.
- For Western Maryland, calculate the projected number of open heart surgery cases in the target year by multiplying the base year open heart surgery use rate for each age group by the target year population in the corresponding year age group in the region.

Step 3: Projection of Total Need for Adult Open Heart Surgery for Washington, D.C. Residents

- Calculate the projected need for adult open heart surgery for Washington, D.C. residents based on the base year actual number of cases incurred by Washington, D.C. residents in Maryland and Washington, D.C. hospitals.

Step 4: Allocation of Total Need for Adult Open Heart Surgery to Service Areas

- Calculate the base year number of open heart surgery cases by region of patient origin by summing the number of residents of each region who underwent open heart surgery in Maryland and Washington, D.C. hospitals in the base year.
- Calculate the base year proportion of patients in each region of residence who received open heart surgery in each Regional Service Area by dividing the number of patients from each region of residence who underwent open heart surgery in each Regional Service Area by the total number of open heart surgery patients from that region of residence.
- Except for Western Maryland, allocate the target year projected number of open heart surgery cases for residents of each region to each Regional Service Area by multiplying the total projected number of cases for residents of each region by the same proportions of allocation.
- For residents of the Western Maryland Regional Service Area allocate 45 percent of the projected number of cases to the Western Maryland Regional Service Area; and allocate the remaining 55 percent to other Regional Service Areas according the base year proportions outlined above.

Step 5: Allocate of Additional Need for Out-of-State Patients

- For all Regional Service Areas, except Western Maryland, allocate to each region the actual number of adult patients from other States, foreign countries, or of unknown residence who underwent open heart surgery in each region in the base year.

Step 6: Calculation of Net Need for Adult Cardiac Surgery Programs

- For each Regional Service Area, calculate the net need for open heart surgery cases by subtracting the total existing capacity from the total projected number of cases.
- Need for an additional cardiac surgery program exists if the net need for open heart surgery cases in a Regional Service Area is at least 200 cases.

Source: COMAR 10.24.17 State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services

Table 6
Comparison of Alternate Use Rate Assumptions on Projected Open Heart Surgery Need

Use Rate Option	Projected (2002) Open Heart Surgery Cases				TOTAL
	Western Maryland	Metropolitan Washington	Metropolitan Baltimore	Eastern Shore	
Option 1: 1997-1999 Trended, Regional Use Rates (Current Methodology)	291	4,033	4,359	615	9,298
Option 2: 1997-1999 Average Regional Use Rates	312	3,938	4,784	569	9,603
Option 3: 1997-1999 Average Statewide Use Rates	292	4,293	4,431	608	9,624
Option 4: Constant Base Year (1999) Regional Use Rates	291	3,935	4,677	576	9,479
Actual Open Heart Surgery Cases (1999)		4,077	4,438	561	9,076

Note: Rounding errors are present in totals

◆ Option 2: 1997-1999 Average Regional Use Rates

Another option for projecting future use rates is to average the recent (1997-1999) experience for each region by age-group. Using the average experience has the benefit of smoothing changes during periods when there are sharp annual fluctuations in use rates. With this modification to the current methodology, the overall volume of projected open heart surgery cases would increase to 9,603 in 2002. This projection results in about 305 additional cases in 2002 when compared with the current methodology.

◆ Option 3: 1997-1999 Average Statewide Use Rates

Using average statewide, rather than regional use rates, is another approach to projecting future use rates. The application of average statewide use rates, when compared with average regional use rates, results in approximately the same volume of total projected cases in 2002. The difference in these two methods occurs in how the projected cases are allocated by planning region. Because the differences in regional use rates between Washington and Baltimore are so great, this method allocates a larger proportion of cases to the Washington region than is the case with the use of average regional use rates.

◆Option 4: Constant Base Year (1999) Regional Use Rates

The impact of no change in current use rates on the future volume of cases is illustrated with this modification to the need projection methodology. If the 1999 use rate experience by age group is maintained in 2002 for each region, there would be about 9,479 total open heart surgery cases.

Table 7
Comparison of Projected and Actual 1999 Use Rates and Open Heart Surgery Cases

	Western Maryland	Metropolitan Washington	Metropolitan Baltimore	Eastern Shore	TOTAL
Projected 1999 Use Rates Per 100,000 Population (1)					
15-44 Years	20.55	14.21	25.36	12.97	
45-64 Years	336.44	206.63	321.02	261.92	
65 Years +	713.83	606.25	1,052.66	590.71	
Actual 1999 Use Rates Per 100,000 Population (1)					
15-44 Years	8.31	12.05	16.33	19.32	
45-64 Years	298.07	195.73	259.45	232.47	
65 Years +	632.32	647.56	794.66	608.38	
Difference Between Projected and Actual Use Rates					
15-44 Years	-59.56%	-15.20%	-35.61%	48.96%	
45-64 Years	-11.40%	-5.28%	-19.18%	-11.24%	
65 Years +	-11.42%	6.81%	-24.51%	2.99%	
Projected 1999 Cases (2)	345	3,858	5,630	517	10,350
Actual 1999 Cases	0	4,077	4,438	561	9,076
Difference Between Projected and Actual		219	-1,192	44	-1,274
% Difference		5.68%	-21.17%	8.51%	-12.31%

(1) The use rates are calculated based on Maryland resident use of open heart surgery services in each planning region.

(2) The projected and actual cases refer to the number of open heart surgery cases performed in each planning region.

3. Measurement of Cardiac Surgery Program Capacity

To determine the need for new open heart surgery capacity, the State Health Plan need projection methodology includes a component that estimates available system capacity. The measurement of program and system capacity, in combination with policies governing the allocation of that capacity, is an important issue in the plan's need projection methodology. Alternative policy approaches to measuring capacity are discussed below.

◆ Option 1: Capacity Based on Physical Operating Room Space

The benchmark used to quantify available system capacity in the current State Health Plan reflects the number of operating rooms dedicated to the open heart surgery program. The current plan identifies 13 ORs dedicated to open heart surgery in Metropolitan Washington cardiac surgery programs and 15 ORs in Metropolitan Baltimore cardiac surgery programs. On the Eastern Shore, 2 ORs are dedicated to open heart surgery. The measurement of the number of open heart surgery cases that can be performed in a single dedicated operating room used in the current plan reflects the assumption that 2.0 cases per day per operating room or 500 cases annually (assuming 5 days per week/50 weeks per year = 250 days) is a reasonable benchmark. This level of utilization is 80 percent of the defined capacity of 2.5 open heart surgery cases per day in a dedicated operating room recommended by the Technical Advisory Committee in 1997. Although there was dissent by two of its 15 members in 1997, the Technical Advisory Committee's measure of capacity suggests that at full use an operating room dedicated to cardiac surgery could perform 625 cases annually.

More recently, the Technical Advisory Committee reconsidered the previous recommendation regarding the capacity benchmark of 2.0 cases per operating room per day. Although there were also dissenting opinions, the Technical Advisory Committee recommended that the capacity benchmark used in the current plan be eliminated and that the measurement of available system capacity be redefined to incorporate other factors such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional open heart surgery programs in Maryland.

Table 8 summarizes the impact of using the current capacity benchmark as well as lower assumptions (400 and 350 cases) about the number of open heart surgery cases that should optimally be performed annually in a dedicated operating room.

Table 8
Comparison of Alternate Open Heart Surgery Capacity Assumptions

Region	Number of Operating Rooms (1)	Capacity Based on Physical Operating Room Space			Capacity Based on Actual Service Utilization (2)	
		500 Cases Per OR	400 Cases Per OR	350 Cases Per OR	Three Most Recent Years	Six Most Recent Years
Western Maryland						
Metropolitan Washington	13	6,500	5,200	4,550	4,347	4,587
Metropolitan Baltimore	15	7,500	6,000	5,250	4,743	4,822
Eastern Shore	2	1,000	800	700	561	561
TOTAL	30	15,000	12,000	10,500	9,651	9,970

(1) The number of operating rooms reflects the existing capacity as indicated on Table 6, COMAR 10.24.17

(2) The greater of 350 cases per hospital or the highest actual annual volume ever attained by a hospital in the three or six most recent years of available data, or if the hospital has not performed, for the past three consecutive years, at least 200 cases per year, the capacity of that program is measured by the actual volume of cases performed in that hospital in the base year.

The use of physical operating room space to measure open heart surgery capacity raises a number of issues. One of those issues concerns whether capacity measurement should reflect historical operating room utilization or, alternatively, the number of cases that could be performed in an operating room at an efficient level of use if demand were present. Because operating rooms are only one component of an open heart surgery service, another issue that must be considered concerns whether the number of operating rooms is the most appropriate measure of overall program capacity. While the number of operating rooms may be a useful proxy for capacity at a specific point in time, this measure does not explicitly consider other important components of an open heart surgery program, including the number of open heart surgery teams and the availability of post-operative care facilities and staff. Because an open heart surgery service is staff rather than capital intensive, it could be argued that operating rooms are not the most appropriate benchmark for capacity. The ability of existing programs to add operating room capacity without CON review is another factor that merits consideration. Although the State Health Plan contains language providing that the published need projection (including the inventory of existing operating room capacity) remains in effect until the Commission publishes updated need projections, the fact that capacity can be increased without approval raises concerns about the use of this measure. The use of dedicated operating rooms as the measure of capacity also does not consider how well the overall system functions to care for patients. On the other hand, operating room capacity is a key component of a cardiac surgery program and the number of dedicated operating rooms can be easily and uniformly measured.

◆Option 2: Capacity Based on Actual Service Utilization

Table 8 also quantifies the impact of measuring capacity based on actual service utilization. In the State Health Plan adopted in 1990, the capacity of existing cardiac surgery programs was defined as follows: the greater of 350 cases per hospital or the highest actual annual volume ever attained by the hospital in the most recent years of accurate available data; or if the hospital had not performed, for the past three consecutive years, at least 200 cases per year, the capacity of that program was measured by the actual volume of cases performed in that hospital during the base year. For comparative purposes, Table 8 includes capacity estimates reflecting the most recent 3 and 6 years of utilization data. It could be argued that basing an estimate of capacity on the actual performance of a program would be more indicative of what volumes are likely to be handled by the program. Using the more recent experience may be preferable to using the older data given that staff associated with the older experience may no longer be available. On the other hand, defining capacity based on utilization measures what has been done rather than what could be done.

5. Patient Migration Patterns

Another key policy assumption in the current methodology used to forecast projected open heart surgery cases concerns patient in and out-migration patterns. In-migration patterns refer to persons receiving cardiac surgical services in Maryland and Washington, D.C. hospitals that lived outside the region. Out-migration patterns refer persons who lived within a particular region and left that region to receive care.

◆Option 1: Constant Patient Migration Patterns Between Base and Target Years

With the exception of the Western Maryland region, where an open heart surgery program is not currently operating, the plan assumes that existing regional patient migration patterns will remain constant between the base and target years of the forecast. For in-migration from adjacent and out-of-state areas to programs in Maryland and Washington, D.C., the current methodology assumes that the actual number of patients will remain constant between the base and target years of the projection. In addition, the methodology assumes that the number of Washington, D.C. residents will remain constant between the base and target years. Because a large number of factors influence where patients go for cardiac care services, actual utilization experience may be the best guide to future utilization patterns in the absence of being able to anticipate specific changes that would influence migration patterns.

◆Option 2: Modified Patient Migration Patterns Between Base and Target Years

An alternative approach to projecting need would be to modify existing migration patterns to change the allocation of future need. While it is anticipated that patients will appropriately travel greater distances to access specialized services, such as open heart surgery, an alternative policy would be to consider establishing a threshold on out-migration for services.

B. Quality of Cardiac Care Policies

1. Minimum and Threshold Utilization Standards

Research on the relationship between volume of specialized cardiac procedures and outcome, as measured by mortality and/or complications, is a dimension of quality that has received considerable attention in planning for open heart surgery services. For cardiac surgery services, a large volume of research studies have suggested lower mortality rates for programs performing higher volumes of procedures. For elective coronary angioplasty services, studies have also shown a greater incidence of complications and/or death in low volume programs as compared with high volume programs. More recently, the volume-outcome relationship has been demonstrated in the treatment of elderly patients with acute myocardial infarction. Because these studies strongly suggest that hospitals providing certain types of specialized cardiac care should have minimum caseloads to ensure quality of care, public policy in Maryland has supported the development of a small number of higher volume programs.

While there is a consensus on the importance of minimum caseloads, there is considerable debate on the factors that account for the relationship between volume and improved outcomes and the strength of that relationship at different performance levels. More recently, the debate has centered on whether greater improvements in outcome extend to programs operating well above recommended minimum caseload levels.

A series of options for establishing minimum and threshold utilization standards for cardiac surgery and therapeutic catheterization programs are outlined and discussed below.

a. Cardiac Surgery Services-Minimum Utilization Standard

◆Option 1: Minimum Utilization Standard of 200 Cases Annually

The current State Health Plan establishes minimum volume standards for cardiac surgical programs. One of those standards indicates that adult cardiac surgical programs should perform a minimum of 200 cases annually to ensure quality of care. Assuming 50 weeks of operation per year, this caseload level is equivalent to performing an average of four cardiac surgery procedures per 5-day week. Recommendations regarding minimum caseloads for open heart surgery were first published by the Inter-Society Commission for Heart Disease Resources in 1972.⁵ The Inter-Society Commission recommended that at least 200 open heart surgery cases be performed annually. In 1991, a joint Task Force of the American College of Cardiology and American Heart Association re-examined this issue and affirmed the previous recommendation of the Inter-Society. This Task Force concluded that hospitals caring for patients requiring surgery for ischemic heart disease should, in general, perform a yearly minimum of 200 to 300 open heart surgery operations, the majority of which are coronary artery bypass operations.⁶ While the minimum utilization standard of

⁵Wright, IS. Frederickson, DT. Eds. Cardiovascular Diseases. Guidelines for Prevention and Care. Reports of the Inter-Society Commission for Heart Disease Resources, 1972.

⁶ American College of Cardiology/American Heart Association Task Force Report, Guidelines and Indications for Coronary Artery Bypass Graft Surgery. *Journal of the American College of Cardiology*. Vol. 17, No. 3. March 1, 1991: 543-589.

200 cases annually used in the current State Health Plan is based on the original work of the Inter-Society, this caseload level continues in practice to be the most universally accepted minimum standard for open heart surgery programs.

◆ Option 2: Minimum Utilization Standard of 100 Cases Annually

An alternative approach to the State Health Plan's current minimum utilization policy for cardiac surgery programs would be to lower the recommended annual volume standard from 200 to 100 cases. This approach could be based on the more recent work of the joint Task Force of the American College of Cardiology and American Heart Association. This joint Task Force examined the relationship between volume and outcome and found that where reporting of outcomes is an accepted practice the relationship between low volumes and mortality seems to have diminished over time. In this analysis, the Task Force recommended that programs performing fewer than 100 cases annually be closely monitored.⁷ The American College of Surgeons has adopted similar guidelines governing caseload volumes. In updated guidelines published in 1997, the College recommended that while 100 to 125 cases per year per hospital appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.⁸

Lowering the minimum utilization standard would also support the view that increased volumes may not necessarily improve outcomes and that factors other than volume may be responsible for differences in patient outcomes. In his presentation before the Technical Advisory Committee in 1999, Dean E. Farley, Ph.D., M.P.A. said that while data from the 1980s show hospitals with higher volume have better outcomes, this data does not answer the question of whether there is a causal relationship or which factor may cause the other. According to Farley, while there may be a correlation between hospital volume and crude mortality rates, the more likely explanations for this correlation are risk differences and selective referral. Scientific proof that practice makes perfect requires rigorous adjustments for differences in risk, correction for selective referral bias, and correlation between volume and outcome over time (not across hospitals). Farley noted that only one study, which he had co-authored, simultaneously tested these three factors.⁹ This study, published in 1992, found that after controlling for selective referral there was no evidence that practice makes perfect. Rather, the correlation between volume and outcome for CABG surgery appears to be due to referral patterns in which hospitals that improve their outcomes attract larger numbers of patients.

⁷ Eagle and Guyton et al. American College of Cardiology and American Heart Association Guidelines for CABG Surgery. *Journal of the American College of Cardiology*. Vol. 34, No. 4, October 1999: 1315-16.

⁸ Guidelines for Standards in Cardiac Surgery. *Bulletin of the American College of Surgeons*. Vol. 82, No. 2, February 1997.

⁹ Farley, DE. Ozminowski, RJ. Volume-Outcome Relationships and Inhospital Mortality: The Effect of Changes in Volume Over Time. *Medical Care*. Vol. 30, No. 1, January 1992: 77-94.

◆ Option 3: Minimum Utilization Standard of 500 Cases Annually

Another approach to minimum volumes would be to increase the standard from 200 to the level of 500 cases annually. Raising the minimum volume threshold for open heart surgery programs would support the view that improvements in outcome are associated with higher volumes of open heart surgery. In his recent analysis for the State of New Jersey, David B. Nash, M.D., M.B.A., found support for the hypothesis that patient outcomes improve as surgical volume increases for both physicians and individual hospitals.¹⁰ This analysis indicates that the minimum CABG volume for hospitals should be set at a level greater than 250 and possibly as high as 800 cases per year. In discussing the volume-outcome relationship before the Technical Advisory Committee, Nash noted that a limitation of current research was the reliance on mortality as the sole measure of outcome. If other measures of outcome were used in this analysis, he indicated that it was likely that improvement in outcome would be demonstrated at higher caseload levels.

b. Cardiac Surgery-Threshold Utilization Standard

◆ Option 1: Threshold Utilization Standard of 350 Cases Annually

The current State Health Plan also establishes a threshold utilization standard which indicates that the establishment of a new cardiac surgery program should permit existing programs to maintain patient volumes of at least 350 cases annually. The use of a threshold standard, in combination with the minimum utilization standard, establishes a policy of requiring programs to perform well above the minimum level of cases before considering the development of additional program capacity. The recommendations prepared by the Technical Advisory Committee in 1999 suggest that cardiac surgery programs should perform at least 350 procedures annually within three years of beginning operation, and that approval of a new cardiac surgery program should not result in any program falling below 350 cases per year.

◆ Option 2: Threshold Utilization Standard Equivalent to the Minimum Utilization Standard

An alternative approach to the current threshold volume standard would be to make this standard equivalent to the minimum utilization standard. This approach would support the viewpoint that while minimum utilization levels are appropriate public policy in planning cardiac surgery services, there would be no additional benefit gained by having existing programs perform above minimum utilization levels. This policy direction would be consistent with encouraging a more market-driven approach relying on competition.

¹⁰ Office of Health Policy at Thomas Jefferson University and Healthcare Research Affiliates, Inc. *Cardiac Surgery in New Jersey*. Submitted to the New Jersey Department of Health and Senior Services and Commissioner Fishman.

Option 3: Threshold Utilization Standard of 800 Cases Annually

Another policy approach to the issue of the appropriate level for the threshold volume standard would be to increase the standard from 350 to 800. In contrast to equating the minimum and threshold utilization standards, this approach would suggest a preference for developing a system of higher volume programs as opposed to a system with a larger number of programs performing at lower or minimum utilization levels.

c. Coronary Angioplasty Services-Minimum Utilization Standard

◆Option 1: Minimum Utilization Standard of 200 Cases Annually

While the current State Health Plan does not establish minimum volume standards for coronary angioplasty programs, guidelines prepared by the American College of Cardiology recommend that hospitals offering coronary angioplasty perform a minimum of 200 procedures annually.¹¹ Those guidelines also suggest that individual physicians perform at least 75 angioplasty procedures annually to maintain competency. If a minimum utilization standard is established for cardiac surgery programs, it could be argued that it is desirable for consistency to establish a minimum utilization standard for elective coronary angioplasty programs. Given that the work of the American College of Cardiology is widely accepted, it would not be unreasonable to consider using 200 elective coronary angioplasty cases as the minimum utilization standard.

◆Option 2: Minimum Utilization Standard of 400 Cases Annually

There is also evidence that suggests that a minimum utilization standard of 400 elective coronary angioplasty cases would not be inappropriate. The 1999 Technical Advisory Committee reviewed seven major studies, using data sources ranging from registries to hospital discharge files, that examined the relationship between the volume of elective coronary angioplasty procedures and outcome. The outcome measures used by these studies include CABG surgery following a failed angioplasty procedure and/or death. Although several of these studies risk adjust outcomes based on whether the patient experienced an AMI, it is important to recognize that these studies refer to elective and not primary angioplasty. All seven of these studies suggest that hospitals performing higher volumes of coronary angioplasty procedures have fewer complications and/or deaths than low volume hospitals. The results from six of the studies indicate that the appropriate minimum volume benchmark is 400 cases annually. One study, reflecting the experience from New York State, suggests that 600 cases annually should serve as the minimum volume standard for hospital coronary angioplasty programs. In their review of these studies, the Technical Advisory Committee pointed out that it is important to recognize that most of these studies were done before the widespread use of stents and potent antiplatelet agents (the GpIIb/IIIa receptor antagonists) which have reduced the incidence of emergency CABG

¹¹ Ryan, TJ. Bauman WB. Kennedy JW. et al. Guidelines for Percutaneous Transluminal Coronary Angioplasty: A Report of the American Heart Association/American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures. *Circulation*. 1993; 88:2987-3007.

following failed angioplasty and death. Thus, while many of these studies report CABG rates of 2 percent or more in the high volume centers, currently this rate is three-fold lower, in the 0.7 percent range. Although there was a dissenting opinion included in their Final Report, the Technical Advisory Committee recommended that coronary angioplasty programs perform a minimum of 400 procedures annually.

d. Coronary Angioplasty: Threshold Utilization Standard

“ Option 1: Threshold Utilization Standard of 600 Cases Annually

The current State Health Plan also does not establish a threshold utilization standard for coronary angioplasty programs. If the threshold standard is used to support a policy of requiring programs to perform well above the minimum level of cases before considering the development of additional program capacity, then it would not be unreasonable to use 600 cases annually as the benchmark.

“ Option 2: Threshold Utilization Standard Equivalent to the Minimum Utilization Standard

An alternative approach to the threshold volume standard would be to make this standard equivalent to the minimum utilization standard. This approach, which was recommended by the Technical Advisory Committee, would support the belief that while minimum utilization levels are appropriate public policy in planning cardiac care services, there would be no additional benefit gained by having existing angioplasty programs perform above minimum utilization levels.

2. Enforcement of Minimum Volume Standards

One of the issues related to minimum volume standards concerns how compliance with these standards should be monitored and enforced.

“ Option 1: Enforce Minimum Volume Standards for New Cardiac Surgery Programs as a Condition of CON Approval

In the current State Health Plan, Policy 1.3 states that a CON issued by the Commission for the establishment of a new cardiac surgery program will require as a condition of issuance that the program achieve minimum volume standards within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. While this policy provides oversight for new cardiac surgery programs, it does not address the issue of existing programs operating below minimum utilization levels.

“ Option 2: Require Cardiac Surgery Programs Operating Below Minimum Utilization Levels to Collect and Report Outcome Data

Another approach to enforcement of minimum utilization standards would be to require programs operating below those standards to review outcomes and submit regular reports to the Commission.

3. Outcome Data Reporting

A number of states have developed and implemented strategies designed to improve the quality of cardiac surgery services over the past decade. The alternative policy approaches to analyzing outcome data for specialized cardiac care services include public reporting of risk-adjusted mortality and morbidity rates and voluntary, collaborative efforts among hospitals and physicians.

“ Option 1: Develop Capability for Public Reporting of Outcome Data for Maryland

One potential approach for Maryland would be to develop the capability for public reporting of outcome data for specialized cardiac care programs. The Commission currently publishes a highly successful report card for Health Maintenance Organizations and has report card projects currently underway for nursing homes, acute care hospitals, and ambulatory surgery facilities. In the area of cardiac care services, New York, New Jersey, and Pennsylvania have pioneered outcome data reporting. New York, for example, began collecting data to analyze the quality of care provided to CABG patients in 1989.¹² As part of this effort, a Cardiac Advisory Committee, composed of surgeons, cardiologists, and researchers, was formed to advise the Department of Health on the quality and appropriateness of cardiac surgery in New York. Since 1990, the Department of Health has annually released hospital-specific data on volumes and mortality rates to the public. In 1992, the publicly released information was expanded to include surgeon-specific risk-adjusted mortality rates. The New York State Department of Health has used the data collected from cardiac care programs as the foundation for a range of quality improvement activities, including the provision of feedback data to hospitals and the development of targeted quality improvement interventions. Similarly, the Pennsylvania Health Care Cost Containment Council initiated the release of public reports on CABG surgery beginning in 1992. These reports, like the reports from New York, contained information about risk-adjusted patient mortality for both hospitals and individual cardiac surgeons. A recent report in this series also includes risk-adjusted mortality and length of stay data for enrollees in selected health plans.¹³ While analyses of the value of public reporting of outcome data suggest numerous positive benefits, there has been a concern that the public availability of this data discourages hospitals from performing cardiac surgery on more complex patients.

“ Option 2: Establish an Independent Consortium to Collect Data and Monitor Outcomes

Another approach to strengthening quality oversight would be to establish an independent consortium to develop data bases for cardiac surgery and angioplasty services and a continuous quality improvement model for specialized cardiac care services. Although there were dissenting opinions, this general approach was discussed by the Technical Advisory Committee in their 1999 report to the Commission. The Northern New England Cardiovascular Disease Study Group, a voluntary research consortium composed of

¹² Hannan, EL Kilburn, H. Racz, M. Shields, E. and Chassin, MR. Improving the Outcomes of Coronary Artery Bypass Surgery in New York State. *Journal of the American Medical Association*. March 9, 1994, Vol. 271, No. 10: 761-766.

¹³ Pennsylvania Health Care Cost Containment Council, *Pennsylvania's Guide to CABG Surgery 1994-1995: Information About Hospitals, Cardiac Surgeons, and Health Plans*. May 1998.

physicians, researchers, and hospital administrators in Maine, New Hampshire, and Vermont, has developed a three-part collaborative approach to reducing CABG mortality that involved: feedback of outcome data; training in continuous quality improvement techniques; and site visits to other medical centers. One assumption of this model is that the health care organizations and systems within which professionals practice can always improve and that one approach to foster this improvement is to establish a process for continuous monitoring and feedback.¹⁴ In Minnesota, cardiac surgery programs have organized a common data base and worked to improve clinical outcomes through a collaborative effort involving detailed analyses of adverse events. The goal of the effort in Minnesota is to provide programs with the ability to benchmark performance and learn from one another.¹⁵

4. Co-Location of Angioplasty and Open Heart Surgery Services

The current State Health Plan for cardiac surgery and therapeutic catheterization services requires that hospitals providing coronary angioplasty services have on-site cardiac surgical backup. This policy was adopted in the 1990 cardiac surgery plan and has been reviewed with the assistance of the Technical Advisory Committee on two separate occasions since its original adoption. The 1997 Technical Advisory Committee, after considerable discussion and review of recent advances in the techniques used to perform angioplasty, concluded:

Although the rate of complications requiring emergency surgery has declined substantially in recent years, the TAC believes that the level of risk associated with performing angioplasty continues to require the presence of on-site cardiac surgical backup.

While the State Health Plan for cardiac surgery and therapeutic catheterization services requires hospitals providing coronary angioplasty services to have on-site cardiac surgical backup, the plan also includes procedures for exempting certain research projects from this policy. Under these exemption procedures, the Health Resources Planning Commission approved a request from Johns Hopkins University to permit selected Maryland hospitals participating in the Atlantic C-PORT primary angioplasty clinical trial to perform angioplasty on certain patients with acute myocardial infarction under the protocols of this research project.¹⁶ Hospitals participating in this clinical trial may perform primary angioplasty without the requirement for on-site cardiac surgical backup. This exemption was originally granted for two years from an effective date of January 15, 1996, and was extended for one year in February 1998. In February 1999, the Commission extended the exemption through February 2001.

Between its initiation and December 1998, the C-PORT Project enrolled more than 400 patients in a randomized clinical trial comparing primary angioplasty with medical therapy. Preliminary results indicate that primary angioplasty can be safely performed without on-site cardiac surgery. No patient enrolled in the clinical trial to date has been referred for emergency coronary bypass surgery because of a complication of the angioplasty procedure. In terms of time to

¹⁴ Donaldson, MS. Ed. *Measuring the Quality of Health Care*. National Roundtable on Health Care Quality. Institute of Medicine, January 1997.

¹⁵ Presentation by Mercedes Dullum, M.D. at the August 24, 1999 Technical Advisory Committee meeting summarizing the meeting of the Society of Thoracic Surgeons on *Regional Development and Organization to Improve the Outcomes in Cardiac Surgery*, July 28, 1999, Chicago, Illinois.

¹⁶ The Atlantic C-PORT Project was initially referred to as the Baltimore C-PORT Project.

treatment, no other large-scale clinical trial published to date has had better randomization-to-first-balloon inflation times than the C-PORT Project. In addition, the outcomes of angioplasty have been excellent with a success rate of 93 percent.¹⁷

The C-PORT Project was originally designed as a randomized clinical trial to compare primary angioplasty with medical therapy in patients with acute myocardial infarction treated at a range of hospital facilities. While early randomized trials were conducted principally in academic medical centers and involved only patients with ST-segment elevation infarction who were thrombolytic candidates, the C-PORT Project extended the comparison to acute myocardial infarction patients with ST-segment elevation considered thrombolytic.¹⁸ At the time the C-PORT clinical trial was originally designed in 1996, there was limited experience in using the technique of coronary angioplasty to treat patients with acute myocardial infarction. Although there remain important questions on the role of primary angioplasty in treating acute myocardial infarction, this therapy has gained widespread acceptance among cardiologists as the preferred approach for treating acute ST-segment elevation myocardial infarction when it can be performed. More recently, the use of primary angioplasty in treating acute myocardial infarction has been further improved and reinforced by the addition of coronary stents and potent antiplatelet agents, the GpIIb/IIIa receptor antagonists. Given these developments, the C-PORT Project stopped randomizing patients in August 1999. Currently, the C-PORT project is operating as a registry.

It is likely that the role of angioplasty versus medical therapy in managing acute myocardial infarction will continue to evolve over the near term and raise a number of important policy issues. Among those issues that should be addressed in the update of the State Health Plan are whether access to primary angioplasty services should be expanded beyond the C-PORT hospitals.

◆Option 1: Maintain Current Policy Requiring On-Site Cardiac Surgery for Angioplasty Procedures with Limited Exemption for Primary Angioplasty

In their recent report, the Technical Advisory Committee recommended that the limited exemption policy permitting hospitals without on-site cardiac surgery backup to perform primary angioplasty under the protocols of the C-PORT project be maintained through 2001. While the Maryland experience with primary angioplasty to date has provided numerous benefits, the Technical Advisory Committee said that sufficient data are not yet available to warrant changing current State health policy to provide all hospitals with cardiac catheterization facilities with the ability to perform limited angioplasty procedures (i.e., primary angioplasty). It would be preferable to use the expertise developed by the C-PORT participants to design and implement a statewide registry that would collect data critical to determining the optimum system of cardiovascular care.

¹⁷ Correspondence from Thomas Aversano, M.D., Associate Professor of Medicine, Johns Hopkins University Hospital, January 12, 1999.

¹⁸ Aversano, T. Primary Angioplasty in the Treatment of Acute Myocardial Infarction. The Strategy of Chest Pain Units in Emergency Departments in the War Against Heart Attacks: Proceedings from the First Maryland Chest Pain Center Research Conference. Supplement to the *Maryland Medical Journal* 88-93.

◆Option 2: Modify State Health Policy to Allow Primary Angioplasty in Hospitals without Cardiac Surgery Programs

An alternative policy direction would be to allow hospitals to perform primary angioplasty procedures without cardiac surgical backup without requiring participation in the C-PORT project. This change in State policy could be based on the view that available data suggests primary angioplasty is a safe and effective treatment that should be available on a more widespread basis. It is not clear how many additional hospitals would offer primary angioplasty services to acute myocardial infarction patients if this change were made to State health policy. Moreover, it is not clear whether there would be a negative impact on primary angioplasty volumes if additional hospitals were to initiate this service. This would be a concern given the findings of a recent study based on data from the National Registry of Myocardial Infarction that found that a higher volume of angioplasty procedures is associated with a lower mortality rate among patients undergoing primary angioplasty.¹⁹

C. Cost of Care Policies

1. Cost Effectiveness Standard

A significant component of the CON review process involves an assessment of the financial feasibility of a project conducted with the assistance of the Health Services Cost Review Commission. The current State Health Plan contains a cost-effectiveness standard that states the Commission will give preference in a comparative review to the applicant which offers the best balance between program effectiveness and costs to the health care system as a whole. This standard has been used to encourage hospitals interested in establishing new cardiac surgery programs to make competitive rate offers to the Health Services Cost Review Commission.

◆Option 1: Give Preference in a Comparative Review to the Hospital with the Most Advantageous Rate Offer to the State

Given an established need for a new cardiac surgery service and similar, competing proposals, the cost effectiveness preference standard in the current State Health Plan encourages applicants to compete to offer the service at the lowest possible price. While the specific wording of this standard must be updated to be consistent with the recent changes to the HSCRC rate setting system, the policy approach has proven viable in the past and resulted in savings to the healthcare system that might not have otherwise been realized. It could also be argued that having new providers to make rate offers has the additional benefit of strengthening competition among existing providers and thus lowering costs throughout the system (i.e., for all patients).

¹⁹ Canto, JG, Every, NR, et al. The Volume of Primary Angioplasty Procedures and Survival After Acute Myocardial Infarction. *The New England Journal of Medicine*. Volume 342, Number 21, May 25, 2000, pp 1573-1580.

◆ Option 2: Eliminate the Cost-Effectiveness Preference Standard

Another policy option would be to eliminate the cost effectiveness preference standard. This approach could be based on the view that market forces (e.g., managed care) currently provide pressure to reduce prices and that system costs (i.e., per capita costs) are more important than unit costs from a public policy perspective.

D. Access to Care Policies

1. Travel Time Standard

Policies governing access to specialized cardiac care services in the State Health Plan focus on both geographic and financial access to care. From the standpoint of geographic access, the plan uses one-way driving time to measure access to existing cardiac surgery programs.

◆ Option 1: Cardiac Surgery Services Should be Located Within 2 Hours, One Way Driving Time for 90 Percent of the Maryland Population

Because cardiac surgery is a specialized health service appropriate for regional planning, a travel time standard of 2 hours, one-way driving time has been used as the benchmark for measuring geographic accessibility. Data included in the current State Health Plan analyzing travel time data to existing cardiac surgery programs indicates that virtually all Maryland residents are within two-hours, one-way driving time to at least one hospital that provides adult cardiac surgery services. Almost 90 percent of the pediatric population are also within two hours, one-way driving time of a facility offering pediatric cardiac surgery services.

◆ Option 2: Cardiac Surgery Services Should be Located Within 90 Minutes, One Way Driving Time for 90 Percent of the Maryland Population

An alternative policy would be to establish a travel time standard of 90 minutes, one-way driving time as the geographic accessibility benchmark.

E. Other Policies

1. Eligibility to Meet Identified New Need

Under the current plan, only hospitals without existing cardiac surgery programs are eligible to apply to meet new need. In other words, if the need projection calculation identifies a net need that is not less than the minimum utilization standard (i.e., 200 cases) then the Commission may consider the establishment of a new program. Although the Commission is not required to approve a new cardiac surgery program with a net need identified, the current plan generally presumes that new need is reserved for new providers as opposed to having existing providers expand capacity to meet that need.

◆Option 1: Limit Eligibility to Meet Identified New Need for Cardiac Surgery Services to Hospitals Without Existing Programs

Given that the number of cardiac surgery operating rooms are not regulated under the CON program, it could be argued that the Commission currently regulates the number of cardiac surgery programs rather than the size or capacity of those programs. This being the case it may be appropriate to establish new programs rather than expand existing programs provided that minimum utilization standards can be met.

◆Option 2: Expand Eligibility to Meet Identified New Need for Cardiac Surgery Services to All Hospitals

From a cost effectiveness perspective, the current plan assumes that applicants in a comparative review for a new cardiac surgery program will make competitive rate offers. If hospitals with existing programs were able to compete to serve future need in this process, it could be argued that there would be additional benefit for the system of cardiac care.

2. Hospital Size

In the series of policies established to guide approval of new cardiac surgery programs, the current plan addresses two aspects of overall facility capacity: (1) the size of the hospital; and (2) the size of the intensive care unit. The size of the hospital is measured by the average daily census for the most recent two years of available data. For the intensive care unit, size is measured by the number of staffed beds. In updating the plan, consideration should be given to whether policies governing the capacity of a hospital that may develop a new cardiac surgery program should be maintained, modified, or eliminated. Three options for establishing policies governing hospital size are outlined below:

◆Option 1: Require Applicants for New Cardiac Surgery Programs to Have an Average Daily Census of at Least 100

Although the Commission may consider evidence as to why this policy should be waived, under the current State Health Plan applicants for new cardiac surgery programs must have an average daily census of 100 patients over the past two years and an 8-bed fully staff ICU. Data for the 12-month period ending in February 2000 indicates that 31 of the 47 licensed acute care hospitals in the State had an average daily census of 100 or more patients. Under this policy, most of the hospitals in the State would be eligible to develop a new cardiac surgery program if need were identified in the State Health Plan.

◆Option 2: Require Applicants for New Cardiac Surgery Programs to Have an Average Daily Census of at Least 200

An alternative approach would be to increase the facility size policy by requiring potential new applicants for cardiac surgery programs to have an average daily census of 200 rather than 100 patients. This policy would limit the number of hospitals that would be eligible to apply for a new open heart surgery program to the

larger facilities. Eleven of the 47 acute care hospitals in the State, including 7 of the 8 Maryland open heart surgery programs, had an average daily census of 200 or more patients during the 12-month period, March 1999-February 2000.

◆ Option 3: Eliminate the Hospital Size Approval Policy

Another approach would be to eliminate this approval policy entirely from the updated State Health Plan chapter. This option could be based on the view that factors other than hospital size are more critical to establishing a successful cardiac surgery program and that the Commission should have the opportunity to consider those factors if the need for additional capacity is identified.

3. Number of New Programs Allowed

The current State Health Plan includes an approval policy that limits the number of new programs that can be approved at one time in each regional service area. Two options for addressing this issue in the updated State Health Plan chapter are outlined below:

◆ Option 1: Permit One New Cardiac Surgery Program at a Time in Each Regional Service Area

A policy that only one new program will be approved at a time in each service area is consistent with the emphasis in the current plan on the need for cardiac surgery programs to meet minimum utilization standards. In this manner, a new program would not have to compete during a startup phase with another new program. On the other hand, it could be argued that if need were sufficient to support more than one program it would be inappropriate not to approve the requisite number of new programs.

◆ Option 2: Eliminate the Limit on the Number of New Programs that Can be Approved at One Time in Each Regional Service Area

Another approach would be to eliminate the policy limiting the number of new cardiac surgery programs that can be approved at one time in each regional service area. This policy option may be consistent with encouraging greater competition among providers of cardiac surgery services.

4. Preference Standards in Comparative Reviews

For comparative CON reviews, the State Health Plan outlines several preference standards in addition to the cost effectiveness standard. Those standards include giving preference to applicants with an established cardiovascular disease prevention and early diagnosis program that includes provisions for educating patients about treatment options; and giving preference to applicants with an established cardiovascular disease prevention and early diagnosis program with particular outreach to minority and indigent patients in the hospital's regional service area. The preference standards provide a tool for encouraging prospective applicants to address important health policy issues.

◆Option 1: Give Preference to Applicants Demonstrating Service to Minority and Indigent Populations and Having an Established Cardiovascular Disease Prevention Program

From a planning perspective, the use of preference standards in a highly competitive, comparative CON review can provide an incentive for hospitals to address important public policy issues. In the area of cardiac care services, for example, use rates for African-Americans have historically been well below those experienced by the non-African American population. While the precise reasons for these differences are not well understood, giving preference to applicants with a demonstrated record of serving minority populations may provide positive results in reducing the disparity in use rates. Because cardiovascular diseases have a number of risk factors that can be effectively addressed through prevention strategies, giving preference in a comparative review to applicants with established disease prevention and early diagnosis programs may also have merit. In addition to these two areas, there may be other types of preference standards that should be included in the updated State Health Plan chapter.

◆Option 2: Eliminate Preference Standards

An alternative policy approach would be to eliminate preference standards from the CON review process. This option could be based on the view that the general CON review criteria and standards are sufficient to evaluate applicants and that preference standards may receive greater weight than appropriate and not necessarily contribute to the selection of the best overall applicant for a new cardiac surgery program.

5. Exemptions from State Health Plan Policies

In 1995, the Health Resources Planning Commission received a request from a cardiologist at Johns Hopkins University for permission to conduct a research study involving primary angioplasty services in community hospitals without on-site cardiac surgical backup. Because the State Health Plan specifically required that angioplasty procedures be performed only in hospitals with on-site cardiac surgery services, this study could not have been conducted without a modification to the planning policies. In considering this issue, the former Health Resources Planning Commission outlined a procedure for granting exemptions from State Health Plan policies. The State Health Plan was subsequently amended to include this exemption policy. In updating the State Health Plan, one of the issues that requires consideration concerns whether the current approach to exempting projects from planning policies should be maintained, modified, or eliminated.

◆Option 1: Provide that the Full Commission May Waive Policies in the State Health Plan for Research Projects for a Limited Time with Conditions

Under the current plan, research projects may be considered for an exemption from certain policies (i.e., planning and program policies) to meet the special needs and circumstances of biomedical research projects which are designed to meet a national need, and for which local conditions offer special advantages. In order to be eligible for this exemption, the plan outlines several conditions: (1) prior to initiation of the project the research proposal must be reviewed by each participating facility's Institutional Review Board; (2) the research proposal must receive a majority of its funding from a

federal agency, other public agency, or private non-profit foundation that has authority over research on human subjects; and (3) the funding agency or foundation must have no financial affiliation with entities that stand to gain economically from the conduct or outcome of the trial. One option would be to maintain this general approach with the current guidelines or a modification of those guidelines. It could be argued that this approach maintains flexibility for the Commission to consider innovative research projects involving emerging technology without compromising important planning policies.

◆Option 2: Eliminate the Provisions Governing Exemptions from State Health Plan Policies

Another approach would be to eliminate the provisions governing exemptions from State Health Plan policies. This policy direction could be based on the view that broad exemptions from State Health Plan policies to accommodate research projects are not appropriate.

6. Relocation of Existing Cardiac Surgery Capacity within Merged Asset Hospital Systems

Consolidation and merger activity in the health care industry is proceeding a rapid pace in Maryland and across the nation. In Maryland, there are now 11 merged hospital systems. These systems, defined as multiple-hospital systems under common management and governance, include about one-half of the 47 licensed acute care hospitals in the State. Incentives to encourage the merger and consolidation of acute care hospitals in Maryland originated from the 1985 Health Care Cost Containment Act-Hospital Mergers and Consolidations.

State health policy favors hospital mergers by providing incentives that exempt certain types of otherwise reviewable projects from the requirement to obtain a CON. The ability to obtain an exemption from the requirement to receive a CON provides an incentive for hospital consolidations and mergers by establishing a more limited, expedited review process for changes in hospital beds or services, and major capital expenditures. The review time period for an exemption from CON review is 45 days, compared by 90 to 150 days in a standard CON review. Although Commission regulations permit interested parties to participate in the review of projects requiring a CON, a review for exemption from CON review does not permit interested parties. An evidentiary hearing may be requested by an applicant or interested party in a standard CON review. For an exemption review, there are no provisions for an evidentiary hearing. While projects requiring a CON may be subject to a batched review based on the published schedule for receipt of applications, the Commission will accept a request for an exemption at any time. In terms of the procedural steps to the final decision, there are also significant differences between projects exempt from CON review versus projects that require a CON. For projects eligible for an exemption, a staff recommendation is considered directly by the Commission. Finally, hospital consolidation and merger projects exempt from CON review must meet three review criteria (i.e., not inconsistent with the State Health Plan, efficient and effective, and in the public interest) as compared to being reviewed based on all applicable State Health Plan review standards and the general CON review criteria.

Given the desire to promote public policy incentives for hospitals to downsize and reconfigure services, an issue that requires consideration in updating the cardiac surgery plan chapter concerns the policy governing the relocation of cardiac surgery services within merged asset systems.

◆ Option 1: Merged Hospital Systems May Not Relocate Any Part of an Existing Cardiac Surgery Program to Another Hospital Within its System without Obtaining a CON

Because the potential relocation or dividing of cardiac surgery programs may result in proliferation of programs in the absence of need and undermine the principles of regional planning for highly specialized services, the policies in the current State Health Plan prohibit the relocation of all or part of an existing cardiac surgery program within a merged asset system without obtaining a CON.

◆ Option 2: Merged Hospital Systems May Reconfigure an Existing Cardiac Surgery Program to Another Hospital Within its System Under the Exemption Process

Another policy approach to this issue would be to increase flexibility for merged asset hospital systems reconfigure cardiac surgery programs without the requirement for a full CON review. This option could be implemented by providing a set of limited circumstances in the updated State Health Plan under which relocations of existing cardiac surgery programs would be considered or by eliminating by current policy and permitting consideration of exemption requests.

IV. SUMMARY

The State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services is designed to ensure that changes in the capacity of the cardiac surgery system are needed and consistent with the Commission's policies. During 2000, the Commission will update this chapter of the State Health Plan. This *White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland* has been prepared to assist the Commission in the plan update process. The paper identifies and examines the potential impact of a range of different policy assumptions. Table 9 summarizes the policy issues discussed in this paper and alternative approaches that could be used in updating the plan. It is the expectation of the Commission that the public comment process involved in updating the plan will identify additional policy options and approaches that merit consideration.

Appendix I

Detailed Tables:

**Total Adult (15 Years +) Open Heart Surgery Cases by Location of Hospitalization and
Jurisdiction of Patient Residence: 1997-1999**

**Open Heart Surgery Use Rates Per 100,000 Population by Age Group and
Jurisdiction of Patient Residence: 1997-1999**

Appendix II

Projected Open Heart Surgery Cases: Target Year 2002 Using Current Need Projection Methodology with Alternate Use Rate Assumptions